REMARKS

Claims 1-4 and 7-10 are currently under examination. Claim 1 has been amended to specify that the claimed method of immunomodulatory therapy includes administering to a mammal an effective amount of one or more components of the cell wall, **but not the entirety of the cell wall,** of *Mycobacterium*. This amendment is supported by the specification page 8, lines 15-23 and page 2, lines 13-16.

Claims 1-4 and 7-9 stand rejected under 102(b) as being anticipated by Qin. The amendments to the claims and the arguments presented herewith overcome this rejection.

As stated in the previously response, in Qin, the efficacy (as defined as protection from spontaneous IDDM in NOD mice) of the following compounds were studied:

- complete Freund's Adjuvant (CFA), an oil/saline emulsion, containing whole killed *Mycobacterium tuberculosis*;
- MDP (Sigma), Muramyl dipeptide, or N-acetylmuramyl-L-alanyl-D-isoglutamine, a peptidoglycan immunoadjuvant originally isolated from bacterial cell wall fragments;
- BCG, (bacillus Calmette-Guerin), an attenuated strain of *Mycobacterium bovis*, administered whole and live.

Qin taught that the use of CFA and BCG was effective, as previously published by others, and as described in the Background of the Invention page 2, lines 7-8 of the specification. However, both of these compounds contain whole *Mycobacterium*. Independent claim 1, as amended, is directed to a method of immunomodulatory therapy using an effective amount of one or more components of the cell wall, **but not the entirety of the cell wall**, of *Mycobacterium*. As disclosed in the specification, applicant has found an effective method of immunomodulatory therapy using only part of the *Mycobacterium* cell wall and not the whole cell wall as in CFA and BCG. Applicant's method does not increase the risk of precipitating a syndrome similar to systemic lupus erythematosus (SLE) in NOD mice, which was associated with the administration of BCG (which contains whole Mycobacterium).

Qin discusses the use of MDP, a compound derived from bacterial cell wall fragments. However, as stated in applicant's previous response, Qin found that MDP did not prevent the onset of diabetes. The Examiner argues that "applicant's remark that Qin's MDP did not prevent the onset of diabetes is not relevant, because [the] instant claims are not drawn to a method of treating diabetes by administering with an MDP, but with one or more Mycobacterium cell wall components." Claim 1 is directed to a method of immunomodulatory therapy using "an **immunomodulating effective** amount of one or more components." Since MDP was shown not to be an **immumomodulating effective component**, its use does not anticipate applicant's claim. Claims 2-4, and 7-9, which depend upon claim 1, are patentable for at least the same reasons as claim 1.

Claims 1 and 10 stand rejected under 35 USC 103(a) as being unpatentable over Qin. Claim 10, which depends upon claim 1, is directed to a method of immunomodulatory therapy in a human using an effective amount of one or more components of the cell wall, **but not the entirety of the cell wall**, of *Mycobacterium*. It is the Examiner's contention that even though Qin does not expressly teach the use of the claimed method in a human, such use would be obvious. As stated above, Qin fails to teach the claimed method in **any mammal**. Further, since Qin failed to determine which individual *Mycobacterium* cell wall components could effectively by used for immunomodulatory therapy, Qin does not disclose or make obvious the use of less than the entirety of the cell for immunomodulatory therapy.

For the foregoing reasons, early action allowing the claims in this application is solicited.

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "**Version with markings to show changes made**".

In the event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit**

Account No. 03-1952 referencing docket no. 229752000600. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,

Dated: March 18, 2002

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claim 1 has been amended as follows:

1. (Twice Amended) A method of immunomodulatory therapy in a mammal said method comprising administering to said mammal an immunomodulating effective amount of one or more components of the cell wall, but not the entirety of the cell wall, of *Mycobacterium*.